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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,141	07/05/2006	Carla Caccia	2503-1218	8827
466 7590 11/27/2009 YOUNG & THOMPSON 209 Madison Street Suite 500 Alexandria, VA 22314			EXAMINER CUTLIFF, YATE KAI RENE	
			ART UNIT 1621	PAPER NUMBER
			NOTIFICATION DATE 11/27/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary

Application No.

10/582,141

Applicant(s)

CACCIA ET AL.

Examiner

YATE' K. CUTLIFF

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11 & 13 - 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 & 13 - 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/22)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

1. Claims 11 & 13 - 17 are pending.
Claims 1 – 10 and 12 have been canceled
Claims 11 & 13 - 17 are rejected.

Response to Amendment

2. The amendment to claims 1, and new claims 15 - 17, submitted September 22, 2009 is acknowledged and entered.

Response to Arguments

3. Applicant's arguments, see pages 10 - 11, filed September 22, 2009, with respect to 35 USC 112, first paragraph rejection of claims 11-14 have been fully considered and are persuasive in view of the claim amendments, cancellations and arguments. The 35 USC 112, first paragraph rejection of claims 11-14 has been withdrawn.
4. Applicant's arguments, see pages 11 - 12, filed September 22, 2009, with respect to 35 USC 112, second paragraph rejection of claim 11 has been fully considered and are persuasive in view of the claim amendment. The 35 USC 112, second paragraph rejection of claim 11 has been withdrawn.

Claim Rejections - 35 USC § 102

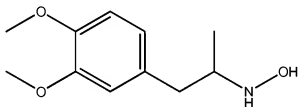
5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Morgan et al. (Tetrahedron, 1975).

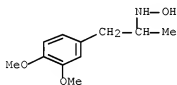
7. The rejected claim is to the following compound:



N-(1-methyl-2-(3,4-dimethoxy-phenyl)-ethyl)-hydroxylamine

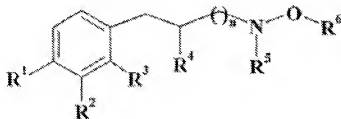
8. Morgan et al. discloses the following compound on page 2598, compound 9.

CN Benzeneethanamine, N-hydroxy-3,4-dimethoxy- α -methyl- (CA INDEX NAME)



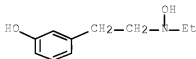
9. Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Korting et al. (Arzneimittel-forschung, 1954).

10. Applicant claims compounds having the following formula:



Further, one of the four (4) separate provisos sets out that when n is 0, R³ is H and R⁴ is H or CH₃, R⁶ cannot be C1-3 straight or branched alkyl. Since the fourth proviso does not further limit R¹, R², R⁵ and R⁶ other than previously identified, they are defined as earlier set out in the claim. Thus, R¹ and R² are H, OH or OCH₃, R⁵ can be H or C1-C5 straight or branched, and R⁶ can be H or C4 – C5, as defined by the claim.

11. Korting et al. discloses the adrenalin derivative phenol, m-[2-(ethylhydroxyamino)ethyl] as set out below.



Applicant is directed to page 64, column 2 compound 5. The claimed compound is anticipated when n=0, R² = OH, R¹, R³, R⁴ and R⁶ = H, R⁵ = C₂H₅ (ethyl).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morgan et al. (Tetrahedron, 1975).

16. The rejected claims cover, inter alia, a pharmaceutical composition of one or more of the compounds of claim 11 in a mixture with suitable excipients and/or carriers.

17. Morgan et al. disclosed the claimed invention. Applicant is directed to the discussion of paragraph 8 above. Morgan et al. discloses that these derivatives are being

studied for their neuropharmacological effects. (see page 2595, col.1, para. 2 introduction). When chemical compounds have very close' structural similarities and similar utilities, without more a prima facie case may be made. (In re Grabiak, 769 F.2d 729, 731, 226 USPQ 870, 871 (Fed. Cir. 1985)). Thus, evidence of similar properties or evidence of any useful properties disclosed in the prior art that would be expected to be shared by the claimed invention weighs in favor of a conclusion that the claimed invention would have been obvious. (Dillon, 919 F.2d at 697-98, 16 USPQ2d at 1905; In re Wilder, 563 F.2d 457, 461, 195 USPQ 426, 430 (CCPA 1977); In re Linter, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972)).

18. Claims 11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morgan et al. (Tetrahedron, 1975).

19. The rejected claims cover, inter alia, a pharmaceutical composition of one or more of the compounds of claim 11 and a compound for the treatment of central and peripheral nervous system disorders.

20. Morgan et al. discloses the claimed invention. Applicant is directed to paragraph 8 above. Further, Morgan states that the compounds are being screened for behavioral and neuropharmacological activity. This is an indication that Morgan is looking at the activity of their compounds on the nervous system.

21. Applicant's claimed pharmaceutical composition includes one or more of the compounds of claim 11 with a compound for treatment of the central or peripheral nervous system.

It would have been obvious to one of ordinary skill in the art at the time of Applicant's claimed invention to recognize with a reasonable expectation of success by incorporating and combining together with the teachings and modifications of Morgan et al. with a compound for the treatment of the central or peripheral nervous system; because Morgan discusses uses of there compound with the nervous system, which broadly includes both the central and peripheral nervous system.

All references above teach compositions and/or methods or processes drawn to use with the nervous system. Morgan et al. teaches an embodiment of the claimed composition with the suggestion that it would be suitable for use as a neuropharmaceutical.

The motivation to combine these references in view of the invention is provided by in re Kerkhoven: "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose [T]he idea of combining them flows logically from their having been individually taught in the prior art. "In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1969, 1972 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents" were held to be prima facie obvious.).

22. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korting et al. (Arzneimittel-forschung, 1954).

23. The rejected claims disclose a pharmaceutical composition of one or more of the compounds of the formula of claim 15 in a mixture with excipients and/or carriers..

24. Korting et al. discloses the claimed invention. Applicant is directed to the discussion in the 102(b) rejection. Korting et al. discloses that the compound has a pharmaceutical use, specifically high pilomotor activity. (see abstract). When chemical compounds have very close structural similarities and similar utilities, without more a prima facie case may be made. (In re Grabiak, 769 F.2d 729, 731, 226 USPQ 870, 871 (Fed. Cir. 1985)). Thus, evidence of similar properties or evidence of any useful properties disclosed in the prior art that would be expected to be shared by the claimed invention weighs in favor of a conclusion that the claimed invention would have been obvious. (Dillon, 919 F.2d at 697-98, 16 USPQ2d at 1905; In re Wilder, 563 F.2d 457, 461, 195 USPQ 426, 430 (CCPA 1977); In re Linter, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972)).

25. Claims 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korting et al. (Arzneimittel-forschung, 1954).

26. The rejected claims cover, inter alia, a pharmaceutical composition of one or more of the compounds of claim 15 and a compound for the treatment of central and peripheral nervous system disorders.

27. Korting et al. discloses the claimed invention. Applicant is directed to the discussion in the 102(b) rejection. Korting et al. discloses that the compound has a pharmaceutical activity by testing the pilomotor activity. (see abstract). Pilomotor responses are mediated by the nervous system.

It would have been obvious to one of ordinary skill in the art at the time of Applicant's claimed invention to recognize with a reasonable expectation of success by

incorporating and combining together with the teachings and modifications of Korting et al. with a compound for the treatment of the central or peripheral nervous system; because Korting et al. discusses uses of there compound in a way that affects a component of the nervous system, which broadly includes both the central and peripheral nervous system.

All references above teach compositions and/or methods or processes drawn to use with the nervous system. Korting et al. teaches an embodiment of the claimed composition with the suggestion that it would be suitable for use as a pharmaceutical.

The motivation to combine these references in view of the invention is provided by in re Kerkhoven: "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose [T]he idea of combining them flows logically from their having been individually taught in the prior art. "In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1969, 1972 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents" were held to be prima facie obvious.).

Conclusion

28. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YATE' K. CUTLIFF whose telephone number is (571)272-9067. The examiner can normally be reached on M-TH 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on (571) 272 - 0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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